



PCT

Receipt

PATENT  
ATTORNEY DOCKET NO. VOSS1130

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Peltonen, *et al.*  
Serial No.: 09/509,595  
Filed: March 28, 2000  
Title: NUCLEIC ACID MOLECULE ENCODING A (POLY)PEPTIDE CO-SEGREGATING IN MUTATED FORM WITH AUTOIMMUNE POLYENDOCRINOPATHY CANDIDIASIS ECTODERMAL DYSTROPHY (APECED)

Art Unit: 1645  
Examiner: Not Assigned

JP.  
1600

Commissioner for Patents  
Office of Initial Patent Examination  
Customer Service Center  
Washington, D.C. 20231

RECEIVED

DEC 14 2000

TECH CENTER 1600/2900

TRANSMITTAL LETTER

Sir:

Transmitted herewith for filing in connection with the above-identified patent application, please find the following:

- (1) Request for Corrected Filing Receipt;
- (2) Filing Receipt reflecting changes;
- (3) Copy of PCT Cover Sheet showing international filing date "October 2, 1998".
- (4) Copy of Response to Notification of Missing Requirements filed on September 5, 2000.
- (5) Return postcard.

CERTIFICATION UNDER 37 CFR §1.8	
I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, <u>10-20, 2000</u> , in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231	
<u>Yiniam N. Najar</u>	
(Name of Person mailing Paper)	
<u>[Signature]</u>	<u>10-20-00</u>
(Signature of Person Mailing Paper)	Date

In re Application: Peltonen, et al.  
Application No.: 09/509,595  
Filed: March 28, 2000  
Page 2

PATENT  
Attorney Docket No. VOSS1130

No fee is deemed necessary in connection with the filing of this paper. However, if any fee is required, the Commissioner is hereby authorized to charge the amount of this fee, or credit any overpayments, to Deposit Account No. 50-1355. A copy of this Transmittal Letter is enclosed.

Respectfully submitted,

Date: 10/20/00



Lisa A. Haile, Ph.D.  
Registration No. 38,347  
Telephone: (858) 677-1456  
Facsimile: (858) 677-1465

GRAY CARY WARE & FREIDENRICH LLP  
4365 Executive Drive, Suite 1600  
San Diego, California 92121-2189



PATENT  
ATTORNEY DOCKET NO. VOSS1130

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Peltonen, *et al.*  
Serial No.: 09/509,595  
Filed: March 28, 2000  
Title: NUCLEIC ACID MOLECULE ENCODING A (POLY)PEPTIDE CO-SEGREGATING IN MUTATED FORM WITH AUTOIMMUNE POLYENDOCRINOPATHY CANDIDIASIS ECTODERMAL DYSTROPHY (APECED)

Art Unit: 1645  
Examiner Not Assigned

Assistant Commissioner for Patents  
Office of Initial Patent Examination  
Customer Service Center  
Washington, D.C. 20231

RECEIVED

DEC 14 2000

TECH CENTER 1600/2900

REQUEST FOR CORRECTION OF FILING RECEIPT

Sir:

This Communication is submitted to request correction of the filing receipt in reference to the above-identified application. The data requiring correction is indicated in yellow highlight on the attached copy of the filing receipt and herein in **BOLD**.

CERTIFICATION UNDER 37 CFR §1.8

I hereby certify that the documents referred to as enclosed herein are being deposited with the United States Postal Service as first class mail on this date, 10-20, 2000, in an envelope addressed to:  
Assistant Commissioner for Patents, Washington, D.C. 20231

Ginia M. Nazar

(Name of Person mailing Paper)

Ginia M. Nazar

(Signature of Person Mailing Paper)

10-20-00  
Date

In re Application: Peltonen, *et al.*  
Application No.: 09/509,595  
Filed: March 28, 2000  
Page 2

PATENT  
Attorney Docket No. VOSS1130

Please correct the following Filing Date of Application Serial No. 09/509,595 from July 5, 2000 to **September 5, 2000**--.

Please correct the International Filing Date of PCT/EP98/06294 from March 28, 1998 to **October 2, 1998** --.

Applicants accordingly request the correction be made of record.

No fee is deemed necessary in connection with the filing of this paper. However, if any fee is required, the Commissioner is hereby authorized to charge the amount of this fee, or credit any overpayments, to Deposit Account No. 50-1355.

Respectfully submitted,

Date:

10/20/00



Lisa A. Haile, Ph.D.

Registration No. 38,347

Telephone: (858) 677-1456

Facsimile: (858) 677-1465

GRAY CARY WARE & FREIDENRICH LLP  
4365 Executive Drive, Suite 1600  
San Diego, California 92121-2189



PATENT  
ATTORNEY DOCKET NO. VOSS1130

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED  
DEC 14 2000

Applicant: Peltonen et al. Art Unit: Unassigned  
Serial No.: 09/509,595 Examiner: Unassigned  
Filed: March 28, 2000  
Title: NOVEL NUCLEIC ACID MOLECULE ENCODING A (POLY)PEPTIDE CO-SEGREGATING IN MUTATED FORM WITH AUTOIMMUNE POLYENDOCRINOPATHY CANDIDIASIS DYSTROPHY (APECED)

BOX PCT  
Assistant Commissioner of Patents  
Washington, D.C. 20231

<p align="center">CERTIFICATE OF MAILING BY "EXPRESS MAIL"</p> <p align="center">"EXPRESS MAIL" MAILING LABEL NO. EL476994339US DATE OF DEPOSIT September 5, 2000</p> <p>I HEREBY CERTIFY THAT THIS PAPER OR FEE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE "EXPRESS MAIL POST OFFICE TO ADDRESSEE" SERVICE UNDER 37 C.F.R. 1.10 ON THE DATE INDICATED ABOVE AND IS ADDRESSED TO THE ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, D.C. 20231.</p> <p align="center">MIKHAIL BAYLEY (TYPED OR PRINTED NAME OF PERSON MAILING PAPER OR FEE)</p> <p align="center"><i>Mikhail Bayley</i> SIGNATURE OF PERSON MAILING PAPER OR FEE</p>
---

RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS

Sir:

In response to the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office mailed June 5, 2000, enclosed are:

1. A copy of the Notification of Missing Requirements;
2. An executed Declaration for Patent Application (5 pages);
3. A Power of Attorney by Assignee (Max-Planck-Gesellschaft zur Forderung der Wissenschaften e.V.; 2 pages);
4. A Verified Statement (Declaration) Claiming Small Entity Status (Max-Planck-Gesellschaft zur Forderung der Wissenschaften e.V.; 1 page);

In re Application of:  
Peltonen et al.  
Serial No.: 09/509,595  
Filed: March 28, 2000  
Page 2

PATENT  
ATTORNEY DOCKET NO. VOSS1130

RECEIVED  
DEC 14 2000


TECH CENTER 1600/2900

5. A Petition for Extension of Time; and
6. Return Postcard.

A check in the amount of \$190.00 is enclosed to cover the two (2)-month extension fee. No other fee is believed to be due in connection with this filing. However, if there are any additional fees required by this filing, the Commissioner is authorized to charge such fees, or credit any overpayments, to Deposit Account No. 50-1355. A copy of the Transmittal Sheet is enclosed.

Respectfully submitted,

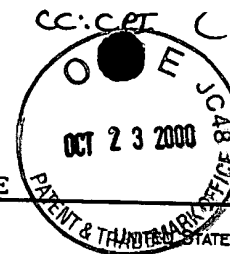
Date: 9/5/00

  
\_\_\_\_\_  
Lisa A. Haile, Ph.D.  
Registration No. 38,347  
Telephone: (858) 677-1456  
Facsimile: (858) 677-1465

GRAY CARY WARE & FREIDENRICH LLP  
4365 Executive Drive, Suite 1600  
San Diego, California 92121-2189



## UNITED STATES PATENT AND TRADEMARK OFFICE



Page 1 of 4

105032-159905

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/509,595	07/05/2000 9-5-2000	1645	1561	VOSS1130	27	1	1

Lisa A Haile  
Gray Cary Ware & Freidenrich  
Suite 1600  
4365 Executive Drive  
San Diego, CA 92121

## FILING RECEIPT



\*OC000000005425090\*

RECEIVED

OCT 03 2000

Date Mailed: 09/25/2000

GRAYCARY/GT PATENT

Receipt is acknowledged of this nonprovisional Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Customer Service Center. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the PTO processes the reply to the Notice, the PTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

## Applicant(s)

Leena Peltonen, Los Angeles, CA ;  
Johanna Aaltonen, Helsinki, FINLAND;  
Petra Bjorses, Helsinki, FINLAND;  
Jaakko Perheentupa, Helsinki, FINLAND;  
Aarno Palotie, Los Angeles, CA ;  
Nina Horelli-Kuitunen, Helsinki, FINLAND;  
Marie-Laure Yaspo, Berlin, GERMANY;  
Hans Lehrach, Berlin, GERMANY;

## Continuing Data as Claimed by Applicant

THIS APPLICATION IS A 371 OF PCT/EP98/06294 03/28/1998-

10-2-1998

## Foreign Applications

GERMANY 97 11 7154.1 10/02/1997  
GERMANY 97 11 7398.4 10/08/1997  
GERMANY 97 11 9810.6 11/12/1997

If Required, Foreign Filing License Granted 09/25/2000

\*\* SMALL ENTITY \*\*

Title

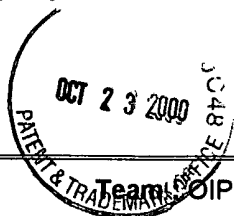
Nucleic acid molecule encoding a (poly)peptide co-segregating in mutated form with autoimmune polyendocrinopathy candidiasis ectodermal dystrophy (apeced)

Preliminary Class

530

Data entry by : ORDENEZ, MARTA

Date: 09/25/2000



RECEIVED

DEC 14 2000

TECH CENTER 1600/2600



PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION  
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(5) International Patent Classification 6 :

C12N 15/12, C07K 14/47, A61K 38/17,  
39/395, G01N 33/68, C12Q 1/68, C07K  
16/18, A61K 48/00

A3

(11) International Publication Number:

WO 99/18197

(43) International Publication Date:

15 April 1999 (15.04.99)

(21) International Application Number:

PCT/EP98/06294

(22) International Filing Date:

2 October 1998 (02.10.98)

(30) Priority Data:

97117154.1

2 October 1997 (02.10.97)

EP

97117398.4

8 October 1997 (08.10.97)

EP

97119810.6

12 November 1997 (12.11.97)

EP

(71) Applicants (for all designated States except US):  
MAX-PLANCK-GESELLSCHAFT ZUR FÖRDERUNG  
DER WISSENSCHAFTEN E.V. [DE/DE]; Berlin (DE).  
NATIONAL PUBLIC HEALTH INSTITUTE [FI/FI];  
Mannerheimintie 166, FIN-00300 Helsinki (FI).

(72) Inventors; and

(75) Inventors/Applicants (for US only): PELTONEN, Leena  
[FI/US]; 1029 Westholme Avenue, Los Angeles, CA  
90024 (US). AALTONEN, Johanna [FI/FI]; Näyttelijäntie  
18 B 22, FIN-00400 Helsinki (FI). BJÖRSES, Petra  
[FI/FI]; Tarkk'ampujankatu 12 A 6, FIN-00150 Helsinki  
(FI). PERHEENTUPA, Jaakko [FI/FI]; Merikatu 3 A  
2, FIN-00140 Helsinki (FI). PALOTIE, Aarno [FI/US];  
1029 Westholme Avenue, Los Angeles, CA 90024 (US).  
HORELLI-KUITUNEN, Nina [FI/FI]; Lauri Mikon-

pojan tie 12 C, FIN-00840 Helsinki (FI). YASPO  
Marie-Laure [FR/DE]; Moltkestrasse 41, D-12203 Berlin  
(DE). LEHRACH, Hans [AT/DE]; Lützelsteiner Weg 50  
D-14195 Berlin (DE).

(74) Agent: VOSSIUS & PARTNER; Siebertstrasse 4, D-8167:  
München (DE).

(81) Designated States: CA, JP, US, European patent (AT, BE, CH  
CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL  
PT, SE).

Published

With international search report.

(88) Date of publication of the international search report:

24 June 1999 (24.06.99)

(54) Title: NUCLEIC ACID MOLECULE ENCODING A (POLY)PEPTIDE CO-SEGREGATING IN MUTATED FORM WITH  
AUTOIMMUNE POLYENDOCRINOPATHY CANDIDIASIS ECTODERMAL DYSTROPHY (APECED)

(57) Abstract

The present invention relates to a nucleic acid molecule encoding a (poly)peptide co-segregating in mutated form with Autoimmune Polyendocrinopathy Candidiasis Ectodermal Dystrophy (APECED). In addition, the invention relates to a mammalian, preferably murine homologue of the above nucleic acid molecule. The present invention further relates to a nucleic acid molecule deviating by at least one mutation from the nucleic acid molecule described above wherein said mutation co-segregates with APECED and is an insertion, a deletion a substitution and/or an inversion, and wherein said mutation further results in a loss or a gain of function of the (poly)peptide encoded by said mutated nucleic acid molecule. Furthermore, the present invention relates to a vector comprising the nucleic acid molecules described above and to a host transformed with said vector. In addition, the present invention relates to a process of recombinantly producing a (poly)peptide encoded by the nucleic acid molecules described above comprising culturing or raising said host and isolating said (poly)peptide from said culture or said host. The present invention further relates to the (poly)peptide encoded by said nucleic acid molecules or produced by the process described above. Additionally, the present invention relates to an antibody that specifically recognizes said (poly)peptides. Moreover, the present invention relates to a method for testing for a carriership for APECED or for a corresponding disease state comprising testing a sample obtained from a prospective patient or from a person suspected of carrying a predisposition for a mutation in the wild-type nucleic acid molecule described above or a mutated form of the (poly)peptide encoded by said mutated nucleic acid molecule in an immuno-assay using the antibody described above.

RECEIVED

DEC 14 2000

TECH CENTER 1600